September 20, 2019

Merge Healthcare Incorporated
% Ms. Lisa Baumhardt
Sr. Regulatory Affairs Program Manager
900 Walnut Ridge Drive
HARTLAND WI 53209

Re: K192276
Trade/Device Name: Merge Cardio
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 21, 2019
Received: August 22, 2019

Dear Ms. Baumhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192276

Device Name
Merge Cardio

Indications for Use *(Describe)*

Merge Cardio software product is an integrated multi-modality image and information system designed to perform the necessary functions required for import, export, review, analysis, quantification, reporting, and database management of digital cardiovascular images, documents, and data related to cardiology. Merge Cardio offers support for third-party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification, and reporting. Merge Cardio software runs on standard information technology hardware and software, using standard information technology operating systems and user interfaces. Communication and data exchange are done using standard protocols. The modular design allows configurability to tailor the image import and communications solution to the needs of the user. The number of modalities and reporting and/or viewing sites can be configured per system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Submitter Information

Submitter: Merge Healthcare Incorporated
900 Walnut Ridge Drive
Hartland, Wisconsin 53209 USA

Date Prepared: August 21, 2019

Contact Person: Lisa M. Baumhardt
Sr. Regulatory Affairs Program Manager
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Secondary Contact: Tracey Fox
RAQA Executive, Regulatory Affairs
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Identification of the Device

Trade Name: Merge Cardio

Common Name: Picture Archiving and Communication System (PACS)

Classification Name: Radiological Image Processing System
21 CFR 892.2050

Product Code: LLZ

Device Class: Class II

Predicate Device(s)

Predicate Device: Vericis Cardiovascular Image and Information System K051649

Device Description

Merge Cardio is a software medical device that is an integrated multi-modality image cardiovascular information management system. The Merge Cardio system is intended to allow authorized health care professionals the ability to import, export, review, analyze, quantify, report and manage digital cardiovascular images, documents, and data related to cardiology. The study list supports workflow management by providing a robust study list with configurable

informational columns supporting navigation, current study and reporting status, and prior study availability and relevancy. The system offers standard image controls such as brightness, contrast, zoom, and cine playback controls; as well modality specific tools such as R-wave sync and frame rate sync. The system allows users to review images, annotate images, perform digital subtraction on XA images, perform quantitative measurements on images (based on modality and anatomy including quantitative coronary analysis, left ventricular analysis, distance, angle, velocity, slope, area, velocity time integral, and volume), derive US measurements, and generate clinical reports. The system provides the ability to create clinical reports for Adult Echo, Pediatric Echo, Vascular US, Nuclear Medicine, Cath/Peripheral Invasive, Electrophysiology, Cardiac CT, and Cardiac MR. Merge Cardio runs on standard information technology hardware and software, using standard technology operating systems and user interfaces. Communication and data exchange are done using standard protocols.

Intended Use/ Indications for Use

Merge Cardio software product is an integrated multi-modality image and information system designed to perform the necessary functions required for import, export, review, analysis, quantification, reporting, and data management of digital cardiovascular images, documents, and data related to cardiology.

Merge Cardio offers support for third-party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification, and reporting.

Merge Cardio software runs on standard information technology hardware and software, using standard information technology operating systems and user interfaces. Communication and data exchange are done using standard protocols.

The modular design allows configurability to tailor the image import and communications solution to the needs of the user. The number of modalities and reporting and/or viewing sites can be configured per system.

Technological Characteristics

Merge Cardio employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence

The modifications to the Merge Cardio device include updates to the software and labeling. The Merge Cardio device has the same intended use and equivalent indications for use as the cleared Vericis Cardiovascular Image and Information System K051649 predicate device. The table below summarizes the changed features being introduced to market:

Comparison to Predicate

Information	Vericis Cardiovascular Image and Information System (K051649)	Merge Cardio V12
Common Name of Device/ Classification/ Product Code	Cardiology PACS 21 CFR 892.2050 LLZ	Cardiology PACS 21 CFR 892.2050 LLZ
Indications for Use	Vericis is a system intended to be used to acquire, store, print, transfer and archive clinical information from Camtronics and other vendors systems including images, Hemodynamic studies and reports, measurements (via import from DICOM Structured Reporting, text files or optical character recognition of measurements captured on images) and cardiology signal (waveform) data. Vericis is intended to allow users to review diagnostic and non-diagnostic quality images, annotate studies, perform digital subtraction on images, to perform quantitative measurements on images (including but not limited to quantitative coronary analysis, left ventricular analysis, time, area, length, velocity, angle, volume, and velocity-time integrals), to generate physician-generated clinical reports (via structured reporting and template based tools), and to store this information in a database. Vericis is software comprised of modules that perform under standard off-the-shelf personal computers and servers running the Microsoft Windows 2000/2003/XP operating system. Vericis is image data storage and display software that accepts DICOM (Digital Imaging and Communications in Medicine) image data files from multiple modalities. It accepts text data using standards-based formats including but not limited to HL7 and XML. Vericis is an Internet/Intranet network system that is designed for small and large, multi-use environments. The Vericis network structure (including server and workstation) provides for the system's database management, storage, printing, and all DICOM/HL7 interface services.	Merge Cardio software product is an integrated multi-modality image and information system designed to perform the necessary functions required for import, export, review, analysis, quantification, reporting, and database management of digital cardiovascular images, documents, and data related to cardiology. Merge Cardio offers support for third-party applications in order to enable the use of commercially available tools and specified applications for analysis, quantification, and reporting. Merge Cardio software runs on standard information technology operating systems and user interface. Communication and data exchange are done using standard protocols. The modular design allows configurability to tailor the image import and communications solution to the needs of the user. The number of modalities and reporting and/or viewing sites can be configured per system.

Information	Vericis Cardiovascular Image and Information System (K051649)	Merge Cardio V12
Features/Specifications	**Vericis (K051649)**	**Merge Cardio V12**
System Overview		
CAS, Workstation (thick client), Web Client (thin client)	Yes	Yes
Software Only	No	Yes
Standard off the Shelf Hardware and Operating System requirements	Yes	Yes
Dual Monitor Support	Yes	Yes, added wide monitor
Speech Recognition	No	Yes
VMware Support	No	Yes
Network	LAN	LAN, MAN, WAN
User Interface	Yes	Yes, updated look and feel and added light/dark themes
CD/DVD	Yes	Yes
Printer	Yes	Yes
Fax	Yes	Yes
Modalities		
Modalities Supported	US, XA, NM	US, XA, NM, IVUS, IVOCT, DX, CR, MR, CT, PET, ECG, EP
System Features		
Study List	Yes	Yes, expanded filters, identification of study status, priors,
Image Review	Yes	Yes, expanded frame rate sync, added ability to view PDFs
Image Enhancement	Yes	Yes
Patient Centric View	No	Yes
Study Annotation	Yes	Yes
Study Editing	Yes	Yes, streamlined workflow
AVI Study Tools	Yes	Yes
Screen Snip Study Tools	No	Yes

Information	Vericis Cardiovascular Image and Information System (K051649)	Merge Cardio V12
Bookmarking Study Tools	No	Yes
Data Imports	Yes, images, non-image data	Yes, images, non-image data, DICOM encapsulated PDFs
US Primitive Measurements	Yes, measured, averaged, imported	Yes, measured, averaged, manual, imported
US Measurement Shapes	Yes	Yes, enhanced workflow
US Derived Measurements	Yes	Yes, added additional derived measurements
US Sticky/Non-sticky measurements	Sticky measurements	Sticky and non-sticky measurements
Reference Measurements	Yes, XA, XRF	Yes, but expanded ability XA, XRF, IVOCT, IVUS
DSA	Yes	Yes
QCA/LVA	Yes	Yes
Clinical Reporting	Yes	Yes, expanded support and improved workflow
Archive and Administration Functions		
Storage	Yes	Yes, added vendor neutral archive
Administrative Reporting	Yes	Yes, added scheduling reports
System Administration Tool	Yes	Yes

Summary of Non-Clinical Tests

The following quality assurance measures were applied to the Merge Cardio system:

- Risk Analysis
- Requirements Review
- Design Reviews
- Unit level code reviews
- Integration testing
- Performance testing

- Safety testing from risk analysis

No performance standards for PACS systems or components have been issued under the authority of Section 514. Non-clinical testing has been performed on Merge Cardio and demonstrates compliance with the following international and FDA-recognized consensus standards and FDA guidance documents:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software -Software life cycle processes
- NEMA-PS 3.1-PS3.20 Digital Imaging and Communications in Medicine (DICOM)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Results from internal verification and validation testing performed in accordance with Watson Health Imaging design control processes confirm that Merge Cardio product specifications have been met. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device.

The subject of this submission, Merge Cardio, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

Summary of Clinical Tests

The subject of this premarket submission, Merge Cardio, did not require clinical studies to support substantial equivalence.

Conclusion

Comparison of the Intended Uses/Indications for Use, the technological characteristics, and performance specifications demonstrate the functional equivalence of the subject device to the predicate device. Verification and validation test results established that the device meets its design requirements and intended uses and that no new issues relative to safety and effectiveness were raised. Watson Health Imaging considers the Merge Cardio to be as safe and as effective as the predicate device, with performance substantially equivalent to the predicate device.